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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/766,688	01/27/2004	Anand Baichwal	540.91195CP5	2079

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EXAMINER	
ROGERS, JAMES WILLIAM	
ART UNIT	**PAPER NUMBER**
1618	

MAIL DATE	DELIVERY MODE
03/18/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/766,688	BAICHWAL, ANAND	
	Examiner	Art Unit	
	JAMES W. ROGERS	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 February 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4,5,7,9,10,14-16 and 18-42* is/are pending in the application.

4a) Of the above claim(s) *31,33-38,41 and 42* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4,5,7,9,10,14-16,18-30,32,39 and 40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Claims 31,33-38 and 41-42 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 02/01/2008.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular claim 1 states a “sustained release excipient” that comprises a gelling agent, an ionizable gel strength enhancing agent and an inert diluent, the limitation is indefinite because the term “sustained release excipient” is singular while applicants claims seem to state that the above ingredients all must be present, thus “excipient” should be referred to in the claim in its plural form “excipients”. Similarly “gelling agent” is singular but the claim limitations states the gelling agent must contain both xanthan and locust bean gum, thus “gelling agent” should be referred to within the claim in its plural form “gelling agents”.

Claim 10 recites the limitation "wetting agents" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Response to Arguments

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-2,4-5,7,9-10,14-16,18-21,24,28-30,32 and 39-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Piergiorgio et al. (US 4,880,623, '623 from hereon, cited by applicants) in view of Baichwal et al. (US 5,128,143, cited previously) in view of Oshlack et al. (US 5,472,712, cited previously).

'623 discloses a process to prepare nifedipine formulations such as tablets by co-precipitating the active with PEG (meets wetting agent) by dissolving the two in a common organic solvent and evaporating the solvent. See abstract col 1 lin 8-17, col 2

lin 39-col 3 lin 20 and claims. '623 also discloses the use of inert excipients such as sucrose, lactose and the like (meets limitation of inert diluent) and can further contain additional modifying agents such as xanthan gum and several cellulose derivatives (meeting limitation of hydrophobic materials).

'623 does not disclose the use of xanthan gum and locust bean gum in combination nor does the reference disclose the use of ethylcellulose as a support platform.

Baichwal discloses sustained release excipient and tablet formulations comprised of xanthan gum and locust bean gum (within the ratio specified by applicants), a moisturizing agent, several inert diluents and a medicament. See col 4 lin 15-col 5 lin 15, col 8 lin 60-63. Regarding the limitation within claim 1 that the ratio of inert diluent to gelling agent is about 1:8 or 8:1, Baichwal discloses that the amount of inert filler is about 30 to about 80% and the amount of hydrophilic material (comprised of xanthan and locust bean gum) is from about 20 to about 70%, thus the ratio of inert filler to hydrophilic material is about 3:7 to 4:1 within applicants claimed range. See col 4 lin 15-lin 23. Regarding claims 7 and 14 Baichwal discloses in the background information the use of hydrophobic materials such as celluloses to control the release of the dose; the concentrations of the cellulose fall within the range specified by applicant. See col 1 lin 37-col 3 lin 10. Also Baichwal discloses the inert diluent can comprise microcrystalline cellulose, the inert diluent is also within the percent range of the hydrophobic material claimed by applicant. See col 8 lin 21-27. Baichwal disclosed that

the combination of xanthan/locusts bean gum provides an excipient with slow release properties for a wide range of relatively soluble and insoluble active ingredients.

Oshlack discloses controlled release formulations (including tablets), which can contain medicaments (including nifedipine) coated with ethyl cellulose and the methods to coat the tablets which includes spray drying. See abstr, col 1 lin 63-col 2 lin 3, col 3 lin 24-34, col 3 lin 55-57 and col 14 lin 20. The limitation of applying a solid support to the tablet is met because the coating of ethyl cellulose in the Oshlack patent obviously gives support to the physical shape and hardness of the tablet, and from the method claims 22,24 and 25 it appears that applicants are referring to a coating since the ethyl cellulose is applied to the surface of the tablet by methods such as spray drying. Regarding claim 10 which is just an experimental optimization of the sequence of adding the ingredients (wetting agent and hydrophobic material) to the mixture, it would be obvious to the skilled artisan to optimize the sequence of adding the ingredients to form the tablet through routine experimentation. See Ex parte Rubin , 128 USPQ 440 (Bd. App. 1959) (Prior art reference disclosing a process of making a laminated sheet wherein a base sheet is first coated with a metallic film and thereafter impregnated with a thermosetting material was held to render prima facie obvious claims directed to a process of making a laminated sheet by reversing the order of the prior art process steps.). See also In re Burhans, 154 F.2d 690, 69 USPQ 330 (CCPA 1946) (selection of any order of performing process steps is prima facie obvious in the absence of new or unexpected results); In re Gibson, 39 F.2d 975, 5 USPQ 230 (CCPA 1930) (Selection of any order of mixing ingredients is prima facie obvious.). The Oshlack patent also

discloses the use of several alkali metal salts that meet the limitations in claim 15 and 16 for an ionizable gel strength enhancing agent because as the applicant states in the specification the ionizable gel strength enhancing agents are used for modifying the release rate of the gel formed from environmental fluids, the Oshlack patent uses the alkali metal salts as pore-formers, which are also release modifiers. Thus it is obvious that since the alkali metal salts serve the same function in the Oshlack patent as within applicants claimed invention the limitation is met. Besides the above remarks the alkali metal salts are the same as within applicant's claims therefore they will have the exact same properties and effect when used in a controlled-release formulation. See col 12 lin 11-24.

It would have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to combine the art described in the documents above because '623 discloses all of applicants claimed invention except for the use of locust bean and xanthan gum in combination as excipients and the use of a solid support while Baichwal and Oshlack described such ingredients in sustained release tablet dosage forms. One with skill in the art would have a reasonable expectation of success in combining the xanthan and locust bean gum excipients of Baichwal and the ethylcellulose support of Oshlack with the formulations of '623 because all the references above are related to the same field of endeavor, sustained release tablet formulations. Thus one of ordinary skill in the art would assume that the excipients and solid support of Baichwal and Oshlack could be combined with the tablet formulations of '623. One of ordinary skill in the art could foresee that by combining the controlled

release excipients in Baichwal and the controlled release coating in Oshlack with '623 the release rate of nifedipine from the dosage form of '623 could be further enhanced or modified. Thus the claimed invention would have been *prima facie* obvious since all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

Claims 1,2,4,5,7,9,10,14-16,18-30,32,39 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Piergiorgio et al. (US 4,880,623, '623 from hereon, cited by applicants) in view of Baichwal et al. (US 5,128,143, cited previously) in view of Oshlack et al. (US 5,472,712, cited previously) in view of Colombo (US 4,839,177, cited previously).

'623, Baichwal and Oshlack are disclosed above and the reason why their combination would have been obvious is incorporated herein. None of the patents above disclose the thickness of the ethylcellulose-support material nor do the references disclose a method of applying the support material by immersion and compression coating.

The Colombo patent is used primarily to show that ethyl cellulose as a support platform and the method to apply it was well known in the art at the time of applicant's invention. Colombo discloses the support thickness within the ranges claimed by applicant; Colombo also discloses all the methods claimed by applicant to apply it unto

the surface (spray drying, immersion and compression coating). See abstr and col 3 lin 13-15.

One of ordinary skill in the art would have a reasonable expectation of success in combining the Colombo patent with the other references above because they are all broadly related to the same field of endeavor, sustained release tablet formulations. Thus one of ordinary skill in the art would assume that the solid support of Colombo could be combined with the tablet formulations disclosed in the combination of references above. Thus the claimed invention would have been *prima facie* obvious since all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

Conclusion

No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to James W. Rogers, Ph.D. whose telephone number is (571) 272-7838. The examiner can normally be reached on 9:30-6:00, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Michael G. Hartley/

Supervisory Patent Examiner, Art Unit 1618